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BRISTOL, LYNN ANNE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,787

Applicant(s)

EISENBACH ET AL.

Examiner

LYNN BRISTOL

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 9/18/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,12-17,21-30,32,33,35-39 and 43-64 is/are pending in the application.
- 4a) Of the above claim(s) 24-29,46-58,60 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,12-17,21-23,30,32,33,35-39,43-45,59 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 3-7, 9 and 12-17, 21-30, 32, 33, 35-39 and 43-64 are all the pending claims for this application.
2. Claim 31 was cancelled, Claims 30, 32 and 33 were amended and new Claims 63 and 64 were added in the Response of 9/18/08.

Claims 63 and 64 are drawn to peptides of SEQ ID NOS: 11 and 25, respectively, which finds literal support in the original specification.

3. Claims 24-29, 46-58, 60 and 61 are withdrawn from examination.
4. Claims 1, 3-7, 9, 12-17, 21-23, 30, 32, 33, 35-39, 43-45, 59 and 62-64 are all the claims under examination.
5. Applicants amendments to the claims have necessitated new grounds for rejection. This action is FINAL.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement (1)

6. The rejection of Claims 15, 21-23, 30 and 43-45 under 35 U.S.C. 112, first paragraph, is maintained as failing to comply with the enablement requirement for an

intended use for treating or inhibiting the development of colon cancer with the inventive MHC-class I binding, CTL-inducing peptides presented as a "cell composition".

For purposes of review the rejection was maintained in the Office Action of 3/18/08 as follows:

"Applicants' allegations on p. 14 of the Response of 1/10/08 have been considered but are not found persuasive. Applicants allege that in amending the claims to replace the limitation "cellular vaccine composition" with "a cell composition" that the claims are fully enabled (or would otherwise remove the requirement that the composition is a vaccine with intended prophylactic properties).

The examiner submits that in requiring the composition (generic Claims 15 and 30) to comprise a "cell composition" comprising "an antigen presenting cell which presents said at least one peptide", Applicants are required to show with a reasonable number of examples that the peptide(s) in fact could be presented by an APC in order to accomplish the required elicitation of a CTL response. The amendment to delete "vaccine" excludes the requirement that the composition is prophylactic, but the compositions still comprise a literal functional component, the APC, which is a) genetically modified with a polynucleotide encoding the TAA peptide, b) loaded with at least one polynucleotide encoding the TAA peptide, c) loaded with TAA peptides and/or d) loaded with polypeptides comprising TAA peptides. The claims embrace recombinant APCs having the ability to express and present the TAA peptide for CTL induction. Applicants' specification does not demonstrate any example of a recombinant APC showing all of the instant claimed characteristics of the compositions. Accordingly, the composition still reads on an intended use where APC is applied in a manner (in vitro or in vivo) to elicit the CTL response that is not fully enabled by the specification at the time of filing."

Applicants' allegations on pp. 10-11 of the Response of 9/18/08 and the 1.132 Declaration have been considered and are not found persuasive. Applicants allege that a reasonable number of working examples for peptide-loaded APCs under the Wands criteria are demonstrated in Example 1 of the specification and the corresponding Tirosh reference (Brit. J. Can. 97:1655-1663 (2007)). Applicants allege one of ordinary skill in the art would expect that if peptides can be presented by APCs using the loading technique(s) mentioned in the present specification, then one of ordinary skill in the art would also expect that they would also be presented using genetic engineering techniques known in the art.

Response to Arguments

The examiner submits that Applicants wish to obtain patent coverage for any peptide of 8-10 amino acid residues in length from any known or yet to be discovered TAA protein expressed by any human colon carcinoma cells formulated into any antigen presenting cell composition. It is clear from the specification and the Tirosh reference that from over 500 putative TAA peptides derived from 26 overexpressed genes in colon carcinoma, that only seven (7) peptides were antigenic and immunogenic in HHD mice. Of these 7, three were from "human 1-8D gene from interferon inducible gene" (peptides 1-6, 3-5 and 3-7), one from actin binding protein (peptide 1-11), one from human ribosomal protein L23a (peptide 2-3), one from TGF-beta induced gene (peptide 3-1) and one human TB2 gene (peptide 3-2). Of these examples, only peptides were loaded into a single kind of APC, RMA/HHD/B7.1, and no examples of a gene-loaded APC are shown. The attorney arguments on the bottom of p. 11 of the Response rely on common knowledge for asserting art-recognized genetic engineering techniques to express peptides from APCs without any indicia of authority for this statement. Pursuant to MPEP 2144.03, "ordinarily there must be some form of evidence in the record to support an assertion of common knowledge."

Furthermore, the Declaration under 37 CFR 1.132 filed 9/18/08 is insufficient to overcome the rejection of claims 15, 21-23, 30 and 43-45 based upon the enablement rejection under 35 U.S.C. 112, 1st paragraph, as set forth in the last Office Action of 3/18/08 because: the Declaration fails to set forth the facts and the showing is not commensurate in scope with the claims for a peptide-loaded APC where the expressed or presented peptide bears all the properties as claimed.

The Declaration does not reference: the outstanding Office Action, the rejected claims and how the rejection is applied to the claims. The Declaration lists two references enclosed as Tirosh et al. Brit. J. Can. 97:1655-1663 (2007) and Eisenbach, Report to Ministry of Health "The effect of SNPs in Tumor Associated Antigens on the Immunogenicity of Peptide Based Vaccines" (pp. 1-8 (8/2007)) without explaining the references or interpreting their relevance to the rejected claims. The Declarant does not explain how the references further support or enable the scope of the rejected claims.

The rejection is maintained because neither Applicants' attorney nor the Declarant has even taken the time to explain with sufficient clarity the relevance of the enclosed references to the instant rejected claims.

Enablement (2)

7. The rejection of Claims 1, 3, 4, 9, 12-17, 21-23, 30, 32, 33, 35-39, 43-45 and 62 under 35 U.S.C. 112, first paragraph, is maintained because the specification is lacking in enablement for any peptide isolated from any protein expressed by any polynucleotide from any human colon carcinoma cell where the peptide has the ability to bind MHC Class I *and* elicit a peptide-specific CTL response and where the peptide optionally includes at least one non-natural modification

For purposes of review the rejection was maintained in the Office Action of 3/18/08 as follows:

A) On pp. 11-13 of the Response of 1/10/08 Applicants allege the claims are fully enabled for the breadth of peptides because: 26 examples of peptides from colorectal genes are shown in Table 2, three peptides derived from 1-8D interferon induced transmembrane protein 2 (SEQ ID NO:59) are shown to be antigenic and immunogenic in HHD mouse model and the working models in the specification provide "sufficient guidance for one of skill in the art to determine other TAA peptides of a protein encoded by a polynucleotide overexpressed in human colon carcinoma

cells without undue experimentation. Applicants then assert that the literature provided as extrinsic support show peptides similarly identified without undue experimentation.

The examiner submits that Applicants' specification as originally filed does not support the breadth of TAA peptides meeting all of the limitations of the instant claims. The overexpressed proteins from colon carcinoma were screened for putative HLA-A2.1 restricted peptides using the "independent binding of individual peptide side-chains" software (Parker et al., 1994). HLA-A2.1-restricted peptides from the selected genes were selected according to its consensus binding motifs as shown in Table 2. Of the 26 peptides, 7 were shown to be immunogenic *in vivo* and 3 peptides were from human 1-8D interferon induced transmembrane protein 2 (SEQ ID NO:59). Not all of the putative peptides in Table 2 were antigenic under assay conditions, only 7 were immunogenic, and 3 of the 7 are all from the same protein (human 1-8D interferon induced transmembrane protein 2). Applicants' own data in the specification are dispositive to the assertion that just any peptide can be designed and that would predictably bind MHC to promote a CTL response *in vitro* much less *in vivo*.

The reference copies provided with the Response are acknowledged but Applicants have not provided any explanation as to how the references are relevant to the instant claimed peptides derived from human colon carcinoma TAA. For example, are any of the reference TAA-derived peptides also described in the specification as overexpressed, colon cancer-derived TAAs?

Machlenkin describes peptides from PAP-3 ((Can. Res. 65:6435-6442 (2005) and (Can. Immunol. Immunother. 56:217-226 (2007)) in prostate cancer and peptides from STEAP from prostate cancer (Can. Res. 65:6435-6442 (2005)). Applicants' claims specifically exclude STEAP-derived peptides so the reference is irrelevant. Applicants' specification teaches "The oldest discovered prostate-restricted antigens have included prostate-specific antigen (PSA), prostate-specific membrane antigen (PSMA) and prostatic acid phosphatase (PAP)" [0140]. How is PAP-3 related to a human colon carcinoma TAA and what is the relevancy of the reference?

Bar-Haim (Br. J. Can. 91:398-407 (2004)) describes peptides from MAGE-A8 protein in bladder cancer. Applicants' specification does not define much less mention MAGE-A8 being a colon cancer TAA. Bar-Haim describes MAGE-A8 protein expression occurring in 44% of colorectal carcinomas but not in any normal colon samples (p. 398, Col. 2, ¶3). Thus MAGE-A8 protein does not even meet the requirements of the claims, which is that the protein is overexpressed, implying that some basal level of expression would need to occur in a normal cell. What is the relevancy of the reference?

Carmon (Int. J. Can. 85:391-397 (2000)) describes peptides from MUC1 protein in breast cancer. Applicants' specification does not define much less mention MUC1 being an overexpressed colon cancer TAA. What is the relevancy of the reference?

Carmon (J. Clin. Invest. 110:453-462 (2002)) describes peptides from BA46 protein in breast cancer. Applicants' specification does not define much less mention MUC1 being an overexpressed colon cancer TAA. What is the relevancy of the reference?

Stepensky (Clin. Exp. Immunol. 143:139-149 (2005)) describes peptides from MUC-1 in lung carcinoma. Applicants' specification does not define much less mention MUC1 being an overexpressed colon cancer TAA. What is the relevancy of the reference?

Applicants have not cited any references that are enabling for the scope of peptides encompassed by the claims at the time of application filing. Applicants have demonstrated that only a small percentage of colon carcinoma TAA-derived peptides modeled from the software program were immunogenic thus one of skill in the art could not reliably and predictably use peptides designed from the software and consensus binding motifs without further experimentation to determine which peptides could bind MHC and elicit a CTL response. The claims further encompass modified peptides, thus the claim scope far exceeds what Applicants have actually demonstrated by working example in the specification or what was known in the art for colon carcinoma-derived immunogenic peptide at the time of filing.

B) On p. 13 of the Response of 1/10/08 Applicants have urged the Office to consider "post-filing experimental results obtained in the laboratory of the present inventors to show that some amino acid modifications of 1-8D peptide 3-7 and all modifications of 1-8D peptide 3-5 induced a CTL response."

The examiner respectfully submits that the data has not been considered because of the improper presentation under MPEP 2162.05 and 37 CFR 1.132:

"§ 1.132 Affidavits or declarations traversing rejections or objections. When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section. [48 FR 2713, Jan. 20, 1983, effective Feb. 27, 1983; revised, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996; revised, 65 FR 54604, Sept. 8, 2000, effective Sept. 8, 2000; revised 65 FR 57024, Sept. 20, 2000, effective Nov. 29, 2000]."

Applicants are invited to resubmit the new data in the form of 1.132 Declaration signed by one of the named inventors and to identify literal support in the original specification for the examples of the modified peptides in order

to avoid raising any issues of new matter. Alternatively, Applicants are invited to file a C-I-P application containing the new data.

C) On pp. 13-14 of the Response, Applicants allege that because the specification describes numerous prophetic or hypothetical examples of non-natural modifications to peptides using positions P1-P9 as guidance, that one of skill in the art could design and model TAA peptides of 8 to 10 amino acid residues from any colon-cancer associated TAA.

The examiner submits that the 7 operative peptides meeting the claim limitations filed in the original specification were not modified from the corresponding stretch of amino acid residues in the corresponding colon cancer protein. All of them corresponded to the native sequence structure from the native protein. Applicants' new data allegedly describes examples of modified peptides for the immunogenic peptides 3-5 and 3-7 from 1-8D interferon inducible protein 2, however, that information has not been considered for the reasons set forth above. Applicants are invited to file the data under a 1.132 Declaration to advance the examination proceeding.

Finally, Applicants specification in Table 2 teaches several non-operative embodiments for peptides which were designed to correspond to native protein structures, and Applicants are now urging the Office to believe that one could further modify a peptide of unpredictable immunogenicity to create an immunogenic, modified peptide absent a proper showing of expected results."

Applicants' allegations on pp. 12-14 of the Response of 9/18/08 and the 1.132 Declaration have been considered and are not found persuasive. Applicants allege that because they have isolated a total of seven immunogenic peptides, that producing and screening immunogenic peptides from any TAA protein expressed by any colon carcinoma is predictable and within ordinary skill; and the "Summary" report discloses 4 variants of peptide 3-7 and 8 variants of peptide 3-5 and which are shown to bind HLA-A2.1 except for the I/A substitution for peptide 3-5.

Response to Arguments

While the specification may enable general methods for selecting and screening a peptide, this does not necessarily place applicant in possession of any overexpressed parent protein from a human colon cancer, an immunogenic peptide from that protein, or a polynucleotide encoding the peptide. The Tirosh reference discloses the same data presented in Example 1 of the specification without expanding on the number or kind of peptides meeting the claim requirements.

The Summary data has been considered but appears to represent new matter. The original specification does not contemplate these peptide variants of SNPs for the

human 1-8D interferon inducible protein 2, and even assuming *arguendo*, they were contemplated it is not predictable that they would function in the manner demonstrated in the Summary report. Additionally, these peptide examples are not further enabling for the infinite genus of peptide classes encompassed by the claims. The Summary Report has not been entered on the PTO 892 form and has been placed in the file. Applicants are requested to identify in the original specification and/or priority document where written description support for the SNP of the human 1-8D interferon inducible protein 2 protein and peptide variants of the SNP is found.

The Declaration under 1.132 is insufficient in overcoming the rejection for the same reasons set forth under section 6 above.

Enablement (3)

8. The rejection of Claims 5, 6 and 59 under 35 U.S.C. 112, first paragraph, is maintained in lacking enablement for any immunogenic peptide derived from the protein encoded by the nucleotide of SEQ ID NO:58 (human 1-8D interferon inducible protein 2) or encoded by the nucleotide of SEQ ID NO: 60 (human 1-8D interferon inducible protein 2 polymorphism).

For purposes of review, the rejection was maintained for the following reasons:

"Applicants' allegations on pp. 14-17 of the Response of 1/10/08 have been considered but are not found persuasive. Applicants allege there is very little difference between the nucleotide sequence of SEQ ID NO: 59 for human 1-8D interferon inducible protein 2 and the nucleotide sequence of SEQ ID NO:60 or the encoded protein thereof (SEQ ID NO: 61) for the polymorphic human 1-8D interferon inducible protein 2 so that the 3 peptides shown in the specification to bind MHC and elicit CTLs (from the protein encoded by SEQ ID NO: 59) would be the same as the peptides from the protein of SEQ ID NO:61 at inducing the response. Further, because the peptide domains for the 3 peptides fall outside of the polymorphic residue(s) of SEQ ID NO:60 and 61, the same 3 immunogenic peptides would occur in the structure of the protein of SEQ ID NO:61 as the protein encoded by the nucleotide of SEQ ID NO:58.

The examiner respectfully submits that the claim scope is not limited to any of the 3 peptides shown in the specification but to any peptide falling within the structure of the protein encoded by the nucleotide of SEQ ID NO:58

(human 1-8D interferon inducible protein 2) or encoded by the nucleotide of SEQ ID NO: 60 (human 1-8D interferon inducible protein 2 polymorphism). The proteins are considered to be separate and distinct because they have different sequence structures."

Applicants' allegations on pp. 14-15 of the Response of 9/18/08 have been considered and are not found persuasive. Applicants reiterate the allegation that just because immunogenic peptides from human 1-8D interferon inducible protein 2 were obtained by following the protocol in the specification, that the ordinary artisan could practice making any other immunogenic peptides without undue experimentation.

Response to Arguments

Applicants' specification and the Tirosh reference do not teach the amount of experimentation required for obtaining peptides from human 1-8D interferon inducible protein 2 and screened for immunogenicity before the 3 functional peptides were identified. What was the total number of peptides from human 1-8D interferon inducible protein 2 required to be generated before the first 3 were identified? Still further, Applicants have ignored the predictability prong of the Wands analysis. The examiner cited several references in the Office Action of 7/10/07 which discussed the unpredictability of selecting CTL immunogenic peptides. Applicants have established they are enabled for 3 peptides obtained from human 1-8D interferon inducible protein 2. Applicants have not established that an immunogenic peptide could be obtained from the SNP for human 1-8D interferon inducible protein 2 encoded by the polynucleotide of SEQ ID NO:61.

The rejection is maintained because Applicants have yet to provide data to support the full scope of peptides encompassed by the claims.

Written Description

9. The rejection of Claims 1, 3-7, 9, 12-17, 21-23, and 62 (and new Claims 63 and 64) under 35 U.S.C. 112, first paragraph, is maintained as failing to comply with the written description requirement because Claims 1, 3-7, 9, 12-17, 21-23, and 62 (and new Claims 63 and 64) recite the negative proviso, "*is not a six transmembrane epithelial antigen of the prostate (STEAP) protein*" in Claim 1, which does not find original support in the specification.

For purposes of review, the rejection was set forth in the Office Action of 3/18/08 as follows:

"The use of a negative limitation is used to define the invention in terms of what it is not, rather than distinctly and particularly claiming a specific peptide or class of peptides that meet the claim requirements and that is supported (and enabled) in the specification. Under MPEP 2173.05(i) "Any negative limitation or exclusionary proviso must have basis in the original disclosure."

The specification defines several putative antigenic peptides derived from proteins associated with human colon carcinoma in Table 2, antigenic peptides in Table 3 and immunogenic peptides (underlined peptides) in Table 3, but does not provide specific written support for the negative limitation "*is not a six transmembrane epithelial antigen of the prostate (STEAP) protein*." Applicants have not and cannot identify per se support in the specification for the negative limitation as presently recited. Applicants are requested to identify the exact page, paragraph and line where the negative proviso is taught in the specification (MPEP 2173.05(ii)). Further, by excluding the peptide(s) of the STEAP class of proteins, the claims encompass myriad other peptides that are not fully supported or enabled by the record evidence. One skilled in the art would conclude that Applicants were not in possession of the invention for any isolated TAA peptide of 8-10 amino acid residues which promotes binding to MHC class, elicits a CTL response, is obtained from a protein overexpressed in human colon cancer, and "*is not a six transmembrane epithelial antigen of the prostate (STEAP) protein*" when instead the only other species of peptides, distinctly and particularly described in the specification are the peptides in Tables 2 and 3."

Applicants' allegations on pp. 15-18 of the Response of 9/19/08 have been considered and are not found persuasive. Applicants excerpt the MPEP under sections 2173.01 and 2173.05(i) and part of the decision from *In re Johnson* 194 USPQ 196 (CCPA 1977) to assert "the positive recitation in the present specification of STEAP indeed provides adequate written description to excise what applicants are not entitled to from their claimed invention by the use of negative limitations."

Response to Arguments

Some earlier cases before *Johnson* were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus In re Schechter, 205 F.2d 185, 98 USPQ 144 (CCPA 1953), the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent.

The examiner submits that Applicants wish to obtain patent coverage for any peptide of 8-10 amino acid residues in length from any known or yet to be discovered TAA protein expressed by any human colon carcinoma cells. It is clear from the specification and the Tirosh reference that from over 500 putative TAA peptides derived from 26 overexpressed genes in colon carcinoma, that only seven (7) peptides were antigenic and immunogenic in HHD mice. Of these 7, three were from "human 1-8D gene from interferon inducible gene" (peptides 1-6, 3-5 and 3-7), one from actin binding protein (peptide 1-11), one from human ribosomal protein L23a (peptide 2-3), one from TGF-beta induced gene (peptide 3-1) and one human TB2 gene (peptide 3-2). Applicants' claims recite a broader genus of protein families than supported by the original disclosure even with the negative proviso.

Thus it is more than apparent that the universe of colon-cancer derived TAA proteins is not supported by the specification much less that any of the 26 proteins examined would necessarily even yield a peptide meeting all of the required limitations

of the claims. Without this specific information, it is impossible to identify the claimed subject matter. Applicants' claims do not exclude these unknown proteins or their corresponding peptides and it is impossible to grant patents rights without a full disclosure of the metes and bounds of the claimed invention. For example, how would another inventor know if one were infringing this claimed invention if the precise epitopes were not disclosed?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The rejection of Claims 30 and 32 under 35 U.S.C. 102(e) as being anticipated by Matsuzaki et al. (US 20030092037; published 5/15/03; filed 7/18/02) is maintained.

For purposes of review, the rejection was set forth in the Office Action of 3/18/08 as follows:

"Claims 30-32 are interpreted as being drawn to a composition comprising a pharmaceutically acceptable carrier or diluent or excipient and a member, where the member is a TAA encoded by human 1-8D interferon inducible gene (Claim 30, element (A) and Claim 31) and the TAA comprises the amino acid sequence of SEQ ID NO: 59 (Claim 32).

Matsuzaki teaches pharmaceutical compositions comprising as the active ingredient a protein having 100% sequence identity to the protein of SEQ ID NO: 59 of instant Claim 32 and which may be combined with other active ingredients or inactive ingredients (e.g., conventional pharmaceutically acceptable carriers or diluents such as immunogenic adjuvants) and physiologically non-toxic stabilizers and excipients [0137]. The sequence search alignment for the protein of Matsuzaki and the protein of SEQ ID NO:59 is attached.

The claimed member appears to be the same as the prior art protein, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989)."

Applicants allege on p. 18 of the Response of 9/18/08 because "Claims 30, 32 and 33, as amended, do not read on a full length TAA, e.g., of SEQ ID NO:59," ...they "cannot be anticipated by Matsuzaki."

Response to Arguments

Initially, the examiner notes that Claim 33 was not an originally rejected claim, and therefore Applicants comments are gratuitous.

Claim 32 recites "wherein said TAA comprises the amino acid sequence of SEQ ID NO:59." SEQ ID NO: 59 is the full length human I-8D interferon induced transmembrane protein 2 (specification, p. 18 [0042]). MPEP 806.04(d) states in part "In general, a generic claim should require no material element additional to those required by the species claims, and each of the species claims must require all the limitations of the generic claim." In other words, generic claim 30 embraces all species claims including Claim 32.

11. The rejection of Claim 30 under 35 U.S.C. 102(e) as being anticipated by *Berger et al.* (US 20030148410; published August 7, 2003; priority to U.S. Provisional Application No. 60/339971, filed December 10, 2001) is maintained.

For purposes of review, the rejection was set forth in the Office Action of 3/18/08 as follows:

"Berger discloses biomarker proteins overexpressed in colon cancer cells compared to normal colon cancer cells comprising 1-8D interferon induced transmembrane protein 2 (IFITM2) (Table 1), for use in compositions [0105] with a pharmaceutically acceptable carrier [0219] or diluent [0242]."

Applicants allege on p. 19 of the Response of 9/18/08 because the claim as amended, does not read on a full length TAA, e.g., of SEQ ID NO:59, it cannot be anticipated by Berger.

Response to Arguments

The disclosure of Berger is of record as disclosing a 1-8D IFN induced transmembrane protein 2 (IFITM2).

Berger also teaches "The antigenic peptide of a protein of the invention, i.e., IFITM2, comprises at least 8 (preferably 10, 15, 20, or 30 or more) amino acid residues of the amino acid sequence (p. 44, lines 9-11 of the provisional application). Accordingly, the peptide size ranges of Berger are overlapping in size range for the instant claimed TAA peptides.

Applicants have not distinguished how the claimed invention differs from Berger.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is indefinite because in depending from Claim 30, it recites a broadening limitation for the TAA of SEQ ID NO:59. Claim 30 is drawn to closed language (i.e., "is...or") for a) the at least one 8-10 residue TAA peptide or b) the polynucleotide encoding the at least one peptide. Therefore it is not clear how the closed language of Claim 30 can include the broadening limitation of Claim 32.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/
Primary Examiner, Art Unit 1643